ATTORNEY DOCKET NO.: P-7326.03 DIV 2

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Total Pages

UTILITY PATENT APPLICATION TRANSMITTAL

FIRST NAMED INVENTOR OR APPLICATION IDENTIFIER: JEAN WOLOSZKO ET AL.
TITLE: MEDICAL ELECTRICAL LEAD

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Via Courier

Sir:

We are transmitting herewith the attached:

X **Patent Application Transmittal**

X **Specification:**
Total pages: 15 (including claims and abstract) :Spec. 10 sheets; Claims 4 sheets; Abstract 1 sheet

X **Drawings:**
Total sheets: 11
☐ formal X informal

Combined Declaration and Power of Attorney:
☐ newly executed
X copy from prior application
☐ Deletion of Inventor(s) - Signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
☐ Incorporation by Reference - *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.*

Accompanying application parts:
☐ Notification of filing a
☐ Assignment of the Invention to Medtronic, Inc.
X Information Disclosure Statement
X Information Disclosure Statement of prior application
X PTO Form 1449 of prior application
☐ Copies of IDS citations
X Preliminary Amendment
☐ A copy of the Petition or Conditional Petition for Extension of Time in the prior application.
X Return Postcard

IF A CONTINUING APPLICATION:

☐ **Continuation** X **Divisional** ☐ **Continuation-in-part (CIP)**
of prior application No. 08/820,473.

☐ **Amend the specification by inserting before the first line the sentence: This application is a ☐ continuation ☐ division ☐ continuation in part of application number__, filed _____.**

☐ **Cancel in this application original claims _____of the prior application before calculating the filing fee. (At least the original independent claim must be retained for filing purposes.)**

X **The prior application is assigned of record to Medtronic, Inc.**

X **The Power of Attorney in the prior application is to: Medtronic, Inc.**

☐ This application claims the benefit of U.S. Provisional Application(s) Serial No.(s) _______, filed __________.

☐ Address all future correspondence to:

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FEE CALCULATION	No. of Claims Filed	Claims Included in Base Fee		No. of Extra Claims	Rate	Fee
Total Claims	06	20	=	02	x 18	$
Independent Claims	01	03	=	02	x 78	$
Multiple Dependent Claims					+ 270	
Basic Filing Fee						$690
					TOTAL	**$690**

X Charge Deposit Account No. 13-2546 the sum of $ 690.00 (Filing Fee) for a total of **$ 690.00.**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

2-24-2000
Date

[signature]
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jean Woloszko et al. | Examiner: L. Cohen

Serial No.: Unassigned | Group Art Unit: 3739

Filing Date: Herewith | Docket No.: P-7326.03 DIV2

Title: MEDICAL ELECTRICAL LEAD

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
Washington, D.C. 20231

Via Courier

Dear Sir:

This preliminary amendment is submitted in conjunction with a new divisional patent application submitted on even date herewith.

I. Amendment

Please amend the above-referenced application as follows:

In the Specification:

On page 2, between lines 2 and 3, after the title and before the words "Field of the Invention," please insert the sentence --This divisional patent application corresponds to co-pending parent U. S. Patent Appln. Serial No. 08/820,473 filed March 17, 1997 for "Medical Electrical Lead" to Woloszko et al.--

In the Claims:

Please cancel claims 7-21. Applicants now elect and reinstate claims 1-6, withdrawn on February 21, 2000 in a Response to Restriction Requirement filed in divisional U.S. Patent Application Serial No. 09/273,457 as being directed to a non-elected invention.

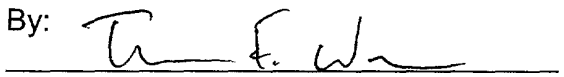
II. REMARKS

This divisional patent application corresponds to and claims the benefit of the filing date of parent U.S. Patent Appln. Ser. No. 08/820,473 filed March 17, 1997 for "Medical Electrical" to Woloszko et al.

Claims 1-6 drawn to a stimulation system is now pending in this divisional application, and is believed to be in condition for allowance. Examination of the application is requested.

The Examiner is respectfully requested to contact the undersigned by voicemail at (612) 514-3652 with any questions or comments he may have.

Respectfully submitted,

By: 

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PATENT
Our File: P-7326.03 DIV2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

TITLE: MEDICAL ELECTRICAL LEAD

INVENTORS: Jean Woloszko
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MEDICAL ELECTRICAL LEAD

FIELD OF THE INVENTION

This invention relates to the field of body-implantable medical device systems, and in particular to a medical electrical lead which features a semi-cylindrical cuff designed to stimulate or sense or both nerve tissue.

BACKGROUND OF THE INVENTION

Modern electrical therapeutic and diagnostic devices, such as pacemakers or nerve stimulators for example, require a reliable electrical connection between the device and the body. In cases of nerve stimulators, in particular, chronically reliable electrical connections have been difficult to attain. In a chronic setting it has been found many medical electrical leads may damage a nerve either mechanically or electrically or both.

Mechanically induced damage includes thickened epineurium due to accumulation of connective tissue between the electrode and the nerve, increased subperineural and endoneural connective tissue, endoneural edema, demyelinization, axonal degeneration and frank axonal loss. Such damage may be caused in several ways. First, if the lead and in particular the electrode which interfaces with the nerve does not move with the nerve, then abrasion may result. Second, the presence of the lead and in particular the electrode, a foreign object, may cause edema or swelling of the nerve. As the nerve swells it may be constricted by the lead. A compressive force may thereby be induced upon the nerve. In the past a so-called "self-sizing" nerve electrode was fashioned to avoid such damage. Such an electrode may be seen in the U.S. Patent No. 4,920,979 to Bullara entitled "Bidirectional Helical Electrode for Nerve Stimulation and assigned to the Huntington Medical Research Institute. To date, however, such electrodes have not been wholly satisfactory.Electrically induced damage may also be caused by a chronic nerve electrode. Such damage results in, among other injuries, axonal degeneration as

well as nerve edema. While it has been shown that the type of electrical stimulation, e.g. frequency, waveform, amplitude, may be a significant factor, the actual electrode design may also affect the degree of electrically induced damage. In particular a medical lead which provides the optimal electrical characteristics for the desired therapy is needed.

SUMMARY OF THE INVENTION

The present invention provides a medical electrical lead for establishing an electrical connection with a tissue of the body. The present invention is particularly suited for use as a nerve electrode and essentially comprises a lead body and a semi-cylindrical cuff. In the preferred embodiment the semi-cylindrical cuff features one or more electrodes. The semi-cylindrical cuff having a long flap which wraps about the cuff and a short flap which wraps about the long flap. The semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively the same stiffness as the long flap. The stiffness of each flap may be varied, however, so that one is more or less than the other, and in turn, than the cuff. Through such a multi-flap construction the electrodes may be positioned proximal to a nerve in such a manner that the mechanically induced damage may be minimized or even entirely eliminated. Finally, a method of implanting such an electrode is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be better understood and appreciated with reference to a detailed description of a specific embodiment of the invention, when read in conjunction with the accompanying drawings.

FIG. 1 depicts a system for nerve stimulation featuring several medical electrical leads.

FIG. 2A is a view of the four leads used in the system of FIG. 1 and the anchoring sleeve and anchoring block which secure the leads.

FIG. 2B is a perspective view of the medical electrical lead.

FIG. 3 is a detailed view of the electrode portion of the medical electrical lead.

FIG. 4A is an exploded view of the electrode portion shown in FIG.3.

FIG. 4B is a sectional view of the electrode portion showing the placement of electrode tabs within the semi-cylindrical cuff.

FIG. 5 is a sectional view of the electrode portion showing the various radial positions of the semi- cylindrical cuff, long flap and short flap.

FIG. 6 is an anchoring sleeve used on the medical electrical lead.

FIG. 7 is an anchoring block used on the medical electrical lead.

FIGS. 8-16 depict the method of implanting the medical electrical lead around the nerve.

FIGS. 17 A, B, and C depict alternative embodiments of the medical electrical lead.

FIGS. 18 A and B depict alternative embodiments of the electrodes used in the medical electrical lead.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a system 1 for nerve stimulation which uses several medical electrical leads of the present invention. As seen, the system features the implantable pulse generator 2 electrically coupled to one or more medical electrical leads 3 by extension cables 4. In the preferred embodiment the pulse generator is the preferred Medtronic model 3025 Sacral Root Stimulator. This device is particularly designed for stimulation of the nerves of the sacral root, although other types of stimulators may also be used. The lead extensions are the Medtronic model 3091 extension cables, although other such devices may also be used. As seen, the system of the preferred embodiment features four medical electrical leads coupled to the implantable pulse generator. The system further preferably features an anchoring sleeve and stabilizing block to maintain the leads in position. These are illustrated below in FIG. 2A.

FIG. 2A is a view of the four leads used in the system of Fig. 1 and the anchoring sleeve and anchoring block which are used to secure the leads. As seen, anchoring sleeve 30 is positioned along the larger diameter section of each lead body of the lead. Positioned distal to the anchoring block is the stabilizing block 35. As seen, stabilizing block is positioned along the thinner diameter section of the lead bodies of the leads. As discussed below, the suture sleeve functions to secure the leads from moving longitudinally relative to one another once they are implanted. Suture sleeve is fastened to the surrounding tissue as is well known. Stabilizing block functions to stabilize each of the distal sections of the leads in position once they are implanted so that implantation of additional leads and the positioning of their electrodes about a nerve will not disturb those leads and electrodes already positioned.

FIG. 2B is a detailed view of a single medical electrical lead 3 according to the present invention. As seen, the lead has essentially three portions, the connector portion 5, the lead body 6, and an electrode portion 7. The connector portion in the preferred embodiment features two pins each of which are electrically coupled to a separate conductor in the lead body. The lead body 6 is preferably constructed of three bundle stranded wire conductors each of which is insulated from the other. The insulation is PTFE, although other types of insulations may also be used, such as silicone.

Positioned at the distal end of the lead body is the electrode portion 7. In the preferred embodiment the electrode portion features three tab electrodes, the inner electrode tab 10 being electrically coupled to a first conductor and the outer two tab electrode tabs 11, 12 electrically coupled to the second conductor of the lead body. In the preferred embodiment the outer two electrode tabs 11, 12 are coupled as anodes while the inner electrode tab 10 is coupled as a cathode. Through this configuration a guarded bipolar electrode is presented to the nerve. A guarded bipolar electrode is preferred because it confines the stimulating current within the

electrode cuff and thereby minimizes the undesired spread of current to the surrounding tissues.

FIG. 3 is a detailed perspective view of the electrode portion. As seen the electrode portion 7 is constructed from three elements. Semi-cylindrical cuff 15 which has an inner long flap 16 mounted to root portion 18 of cuff so as to extend about the opening of the semi-cylindrical cuff. Due to the orientation of the long flap relative to the semi-cylindrical cuff, the lumen is defined. Enveloping the outer end portion of the long flap, is an outer short flap 17. Through this configuration the self-sizing cuff is formed which permits the cuff to stay mounted around the nerve and not be dislodged through the swelling of the nerve. Positioned within the interior surface of the semi-cylindrical cuff are three tab electrodes (only one of which is seen as 12.)

FIG. 4A is an exploded view of the electrode portion. As seen, the electrode portion features a semi-cylindrical cuff. The semi-cylindrical cuff has three cylindrical grooves 20-22 on the inner surface. Three tab electrodes 10-12 are positioned in the grooves. The tab electrodes are preferably constructed from a platinum-iridium alloy, although other materials may also be used such as a conductive polymer. Extending in the opposite radial direction of the semi-cylindrical cuff 15 is the long flap 16. The long flap has a cylindrical design. Extending in the same direction of the semi-cylindrical cuff (and thus opposite radial direction of the long flap) is the short flap 17. The short flap also has a cylindrical shape. In the preferred embodiment the semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively more stiff than the long flap. Of course, the relative stiffness of the flaps in the cuff may be different. Located at the radial distal end of the semi-cylindrical cuff is a suture hole 23 which may be used to manipulate the cuff during the implant process, described below.

FIG. 4B is a longitudinal cross-section of semi-cylindrical cuff. As seen, electrode tabs 10, 11 and 12 are positioned within cuff recesses in the cuff. Recesses are dimensioned such that there is an overlap of material along the edges

of each electrode tab. Through this overlap the electrode tab is mechanically secured within the cuff. In the preferred embodiment overlap area is 0.2 inches in length on each side and the exposed area is 0.6 inches in length. Each electrode tab is positioned in the recess to a depth corresponding to the center of the cuff thickness.

FIG. 5 shows the relative radial orientations of the flaps and the semi-cylindrical cuff. As seen, the semi-cylindrical cuff 15 extends for approximately 180°, although other radial lengths may also be used, including from 270° to 90°. Moreover, although depicted in the figures as a cylindrical design, this cuff may also have other designs, such as square or octagonal, for example, and may also be of other designs entirely, such as helical. The long flap 16 preferably extends in a radial direction opposite of the semi-cylindrical cuff for an amount of 340°, although other radial lengths may also be used, such as between 360° - 180°. The short flap 17, in turn, extends in the same radial direction as the semi-cylindrical cuff and preferably extends for a radial distance of 120°, although other radial distances may also be used, including anywhere between 45° - 360°. Through this construction, the relative radial directions and distances of the semi-cylindrical cuff and the flaps, as well as through various stiffnesses, the self-sizing property of the electrode portion is provided. Self-sizing property is an essential aspect of the present invention because it permits the electrode to accommodate swelling of the nerve without damaging the nerve while maintaining electrical contact. Moreover, partial dislodgment due to pulling or movement of the electrode portion from the nerve is automatically controlled through the elastic property of the flaps, i.e. the electrode re-seats itself back onto the nerve it has partially dislodged.

FIG. 6 is the suture sleeve used in the system of FIG. 1 and clearly shown in FIG. 2A. As seen, the suture sleeve 30 has a body 31 having a lumen 32 therethrough. The lumen is shaped to accommodate four cylindrical lead bodies therein although less lead bodies can also be positioned therein. The suture grooves 33 on the body permit the body to be cinched or tied to the lead bodies. The

suture hole 34 permits the body to be sutured to the surrounding tissue. The suture sleeve functions to secure the leads from moving longitudinally as indicated by arrow 198.

FIG. 7 depicts the stabilizing block used in the system of FIG. 1 and clearly shown in FIG. 2A. The stabilizing block 35 preferably has four slots 36-39 to accommodate four lead bodies. Slots are accessed by the four leads by bending block in direction 44. Slots are dimensioned in their bottom to correspond to and frictionally engage with lead body although they may also have other shapes, e.g. rectangular. Tabs 40 extend from the block to permit the block to be sutured into the surrounding tissue using holes 41. Stabilizing block stabilizes each of the electrode portions 7 of each lead from moving out of position while the outer leads are implanted.

FIGS. 8 -16 depict the method of implanting the present invention. As seen in FIG. 1, the nerve 50 is surgically exposed and elevated from its position using two nerve hooks 51. As seen in FIGS. 9 and 10 forceps 52 are used to gently pull the short flap 17 from its biased position while holding the electrode portion 7 by the lead body. Next, using another pair of forceps 53 the long flap 16 is gently removed from its biased position so the opening of the half cuff 15 is exposed.

Turning to FIG. 13, using the two forceps, 52, 53 the two flaps 16, 17 are moved in opposite linear directions in order to incline the half cuff and present the tab electrodes for contact to the nerve. This is depicted in FIG. 14. Once correctly positioned, the long flap is released and permitted to extend back to its original position around the cuff. Once correctly positioned, the short flap is then released to wrap about the exterior of the long flap.

FIG. 16 shows an alternative method of presenting the tab electrodes to the nerve. In this method a single forceps 60 is used to hold the flaps 16, 17 and a suture 61 is strung through the semi-cylindrical cuff suture hole. The suture is then used to manipulate the cuff so that the tab electrodes are properly positioned about the nerve. Once the electrode portion is properly positioned, the nerve is released,

the lead body and conductor are properly positioned and contacted to the stimulator and the incisions are closed, as well known.

FIGS. 17 A, B and C disclose alternative embodiments of the electrode portion. FIG. 17A shows a semi-cylindrical cuff 15 having a long flap 16 which is substantially 360° in length, a short flap which is substantially 135° in radial length. The cuff 15 is approximately 90° in radial length. Suture hole portion 14 of cuff is shaded and it does not contribute to the actual radial length of cuff 15. FIG. 17B is a further alternative embodiment in which the cuff 15 has a radial length of 180°, the long flap 16 has a radial length of 270° and the short flap 17 has a radial length of 180°. FIG. 17C is a further alternative embodiment in which the cuff 15 has a radial length of 270°, the long flap 16 has a radial length of 180° and the short flap 17 has a radial length of 270°.

FIGS. 18A and B depict alternative embodiments of the electrodes used in the medical electrical lead of the present invention. FIG. 18A is a view of a semi-cylindrical cuff 116 shown as if it was flattened into one plane. Of course, cuff 116 is meant to be cylindrical in use and is illustrated only as a plane for purposes of clearly showing the electrode tab configuration. As seen, tabs are disposed longitudinally along cuff 116, the inner electrode tab 110 being electrically coupled to a first conductor and the outer two electrode tabs 111, 112 electrically coupled to a second conductor within a lead body 106. Turning now to FIG. 18B a further alternative embodiment is shown. As seen in this embodiment, inner electrode is composed of two or more electrode areas 210A and 210B. Outer electrode areas are comprised by two or more electrode areas 212A, 212B and 211A and 211B respectively. Areas 210 are coupled to a first conductor in the lead body 206 while areas 212 and 211 are coupled to a second conductor in the lead body. In this embodiment the surface area of the electrode areas 212 and 211 added together equal the total surface area of electrode 210. In each of the embodiments shown in FIG. 18B the electrodes may be formed from a bio-compatible metal, such as a platinum iridium alloy, but may also be formed from a conductive polymer.

Although the invention has been described in detail with particular reference to a preferred embodiment and alternate embodiments thereof, it will be understood variations and modifications can be effected within the scope of the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

We claim:

1. A system for providing medical electrical stimulation comprising: a first medical electrical lead having a first lead body and a first electrode portion, the first electrode portion coupled to the first lead body, the first lead body having a first proximal section and a first distal section, the first distal section thinner than the first proximal section.

2. A system for providing medical electrical stimulation according to claim 1 further comprising: a second medical electrical lead having a second lead body and a second electrode portion, the second electrode portion coupled to the second lead body, the second lead body having a second proximal section and a second distal section, the second distal section thinner than the second proximal section;

a suture sleeve position on each proximal end of the lead bodies; and

a stabilizing block positioned on the distal end of the lead bodies, the stabilizing block having means for stabilizing each of the electrode portions of the lead from moving out of position once they have been implanted while the other leads are being implanted.

3. A system for providing medical electrical stimulation according to claim 2 wherein the means of stabilizing comprise a pliant polymer block having a series of slots, the slots dimensioned to frictionally engage with the each lead body.

4. A system for providing medical electrical stimulation according to claim 2 wherein the electrode portion comprises a root portion, a semi-cylindrical cuff extending from the root portion in the first radial direction, a long flap extending from the root portion in a second radial direction, the long flap extending over at least a portion of the semi-cylindrical cuff, and a short flap extending from the root portion in a first radial direction, the short flap extending over at least a portion of the long flap.

5. A system for providing medical electrical stimulation according to claim 4 further comprising the first radial direction between 90 and 270 degrees.

6. A system for providing medical electrical stimulation according to claim 5 further comprising the second radial direction between 180 and 360 degrees.

7. A medical electrical lead comprising: a lead body having a first conductor covered by an insulation, the lead body having a proximal end and a distal end; a cuff assembly coupled to the distal end of the lead body, the cuff assembly having a semi-cylindrical cuff having a first, second and third recesses therein, a first tab electrode positioned at the bottom of the first recess, a second tab electrode positioned at the bottom of the second recess, a third tab electrode positioned at the bottom of the third recess, wherein each recess has an overhang, the overhang partially covering at least a portion of at least two sides of each tab electrode, wherein the first and third tab electrodes are coupled to the first conductor.

8. A medical electrical lead according to claim 7 further comprising the lead body having a second conductor, the second tab electrodes coupled to the second conductor.

9. A medical electrical lead according to claim 7 wherein the recess extends from an inner surface of the cuff to a depth corresponding to the midpoint of the cuff thickness, the tab electrode positioned at the midpoint of the cuff thickness at the bottom of the recess.

10. A medical electrical lead according to claim 7 further comprising the cuff assembly having a root portion, the semi-cylindrical cuff extending from the root portion in a first radial direction, a long flap extending from the root portion in a

second radial direction, the second radial direction opposite the first radial direction.

11. A medical electrical lead according to claim 10 wherein the long flap extends over at least a portion of the semi-cylindrical cuff.

12. A medical electrical lead according to claim 10 further comprising a short flap extending from the root portion in the first radial direction, the short flap extending over at least a portion of the long flap.

13. A medical electrical lead according to claim 10 further comprising the first radial direction between 90 and 270 degrees and the second radial direction between 180 and 360 degrees.

14 A nerve cuff electrode comprising

a semi-cylindrical cuff, the semi-cylindrical cuff having a longitudinal axis and an inner surface, a first recess within the inner surface, the first recess not parallel to the longitudinal axis, the first recess having a bottom surface and opposing side walls, the first recess having a first width, the first width greater between the side walls nearest the bottom surface and smaller between the side walls nearest the inner surface such that a opposing pair of shoulder overhangs are present, a tab electrode positioned within the recess such that opposing pair of shoulder overhangs cover side portions of electrode to thereby mechanically maintain electrode within the recess.

15. A medical electrical lead according to claim 14 further comprising the lead body having a second conductor, the second tab electrodes coupled to the second conductor.

16. A medical electrical lead according to claim 14 wherein the recess extends

from an inner surface of the cuff to a depth corresponding to the midpoint of the cuff thickness, the tab electrode positioned at the midpoint of the cuff thickness at the bottom of the recess.

17. A medical electrical lead according to claim 14 further comprising the cuff assembly having a root portion, the semi-cylindrical cuff extending from the root portion in a first radial direction, a long flap extending from the root portion in a second radial direction, the second radial direction opposite the first radial direction.

18. A medical electrical lead according to claim 17 wherein the long flap extends over at least a portion of the semi-cylindrical cuff.

19. A medical electrical lead according to claim 17 further comprising a short flap extending from the root portion in the first radial direction, the short flap extending over at least a portion of the long flap.

20. A medical electrical lead according to claim 17 further comprising the first radial direction between 90 and 270 degrees and the second radial direction between 180 and 360 degrees.

21. A medical electrical lead according to claim 17 further comprising the semi-cylindrical cuff further comprising second and third recesses therein, a first tab electrode positioned at the bottom of the first recess, a second tab electrode positioned at the bottom of the second recess, a third tab electrode positioned at the bottom of the third recess

ABSTRACT

A medical electrical lead for establishing an electrical connection with a tissue of the body, the lead having a lead body and a semi-cylindrical cuff. In the preferred embodiment the semi-cylindrical cuff features one or more electrodes. The semi-cylindrical cuff having a long flap which wraps about the cuff and a short flap which wraps about the long flap. The semi-cylindrical cuff is relatively stiff as compared to the short flap. The short flap, in turn, is relatively the same stiffness as the long flap. The stiffness of each flap may be varied, however, so that one is more or less than the other, and in turn, than the cuff. Through such a multi-flap construction the electrodes may be positioned proximal to a nerve in such a manner that the mechanically induced damage may be minimized or even entirely eliminated. Finally, a method of implanting such an electrode is also disclosed.

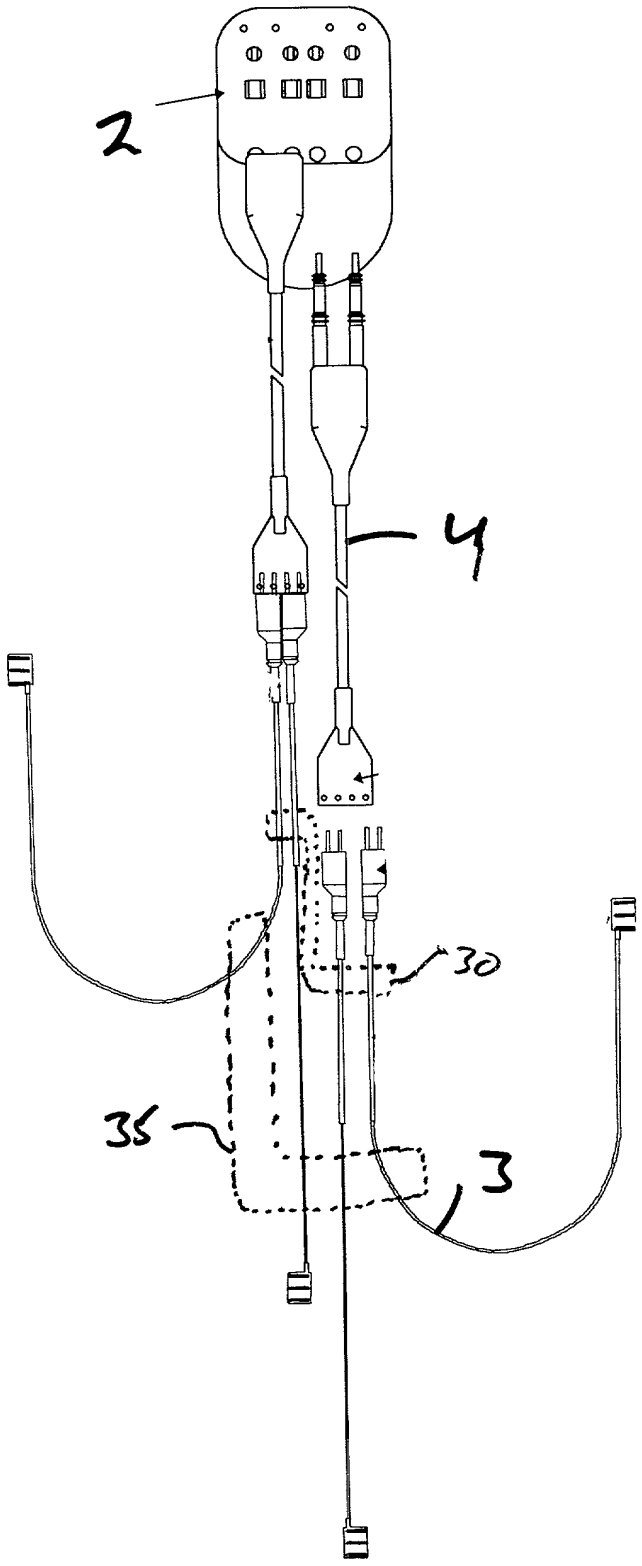


Fig 1

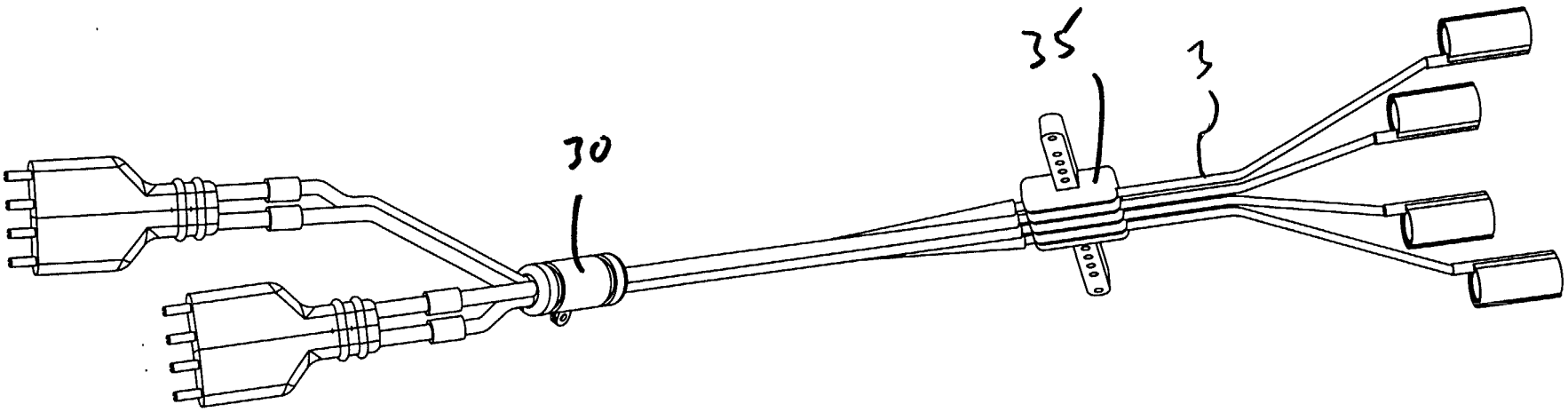


FIG 2A

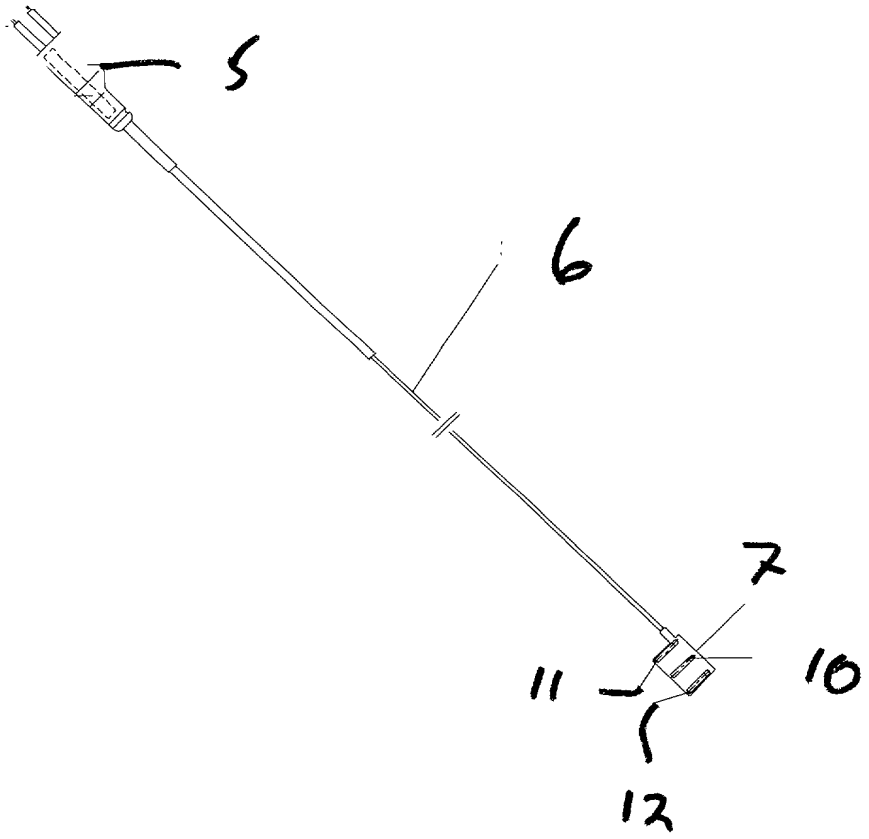


Fig 2B

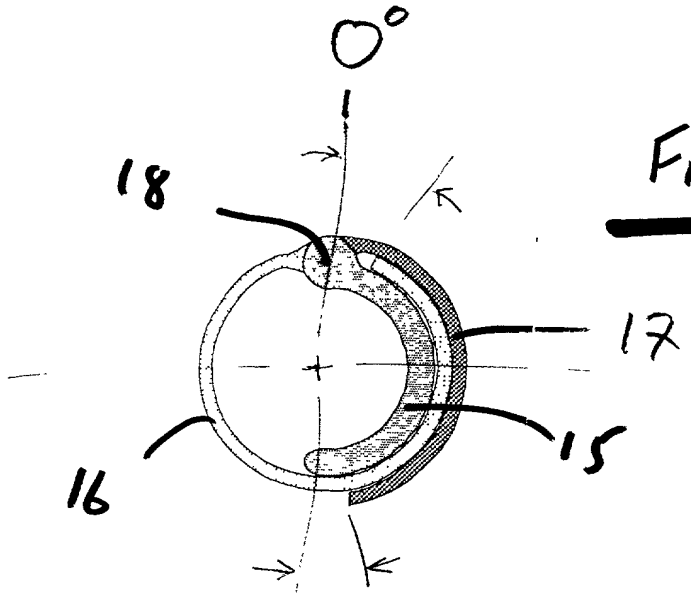


Fig 5

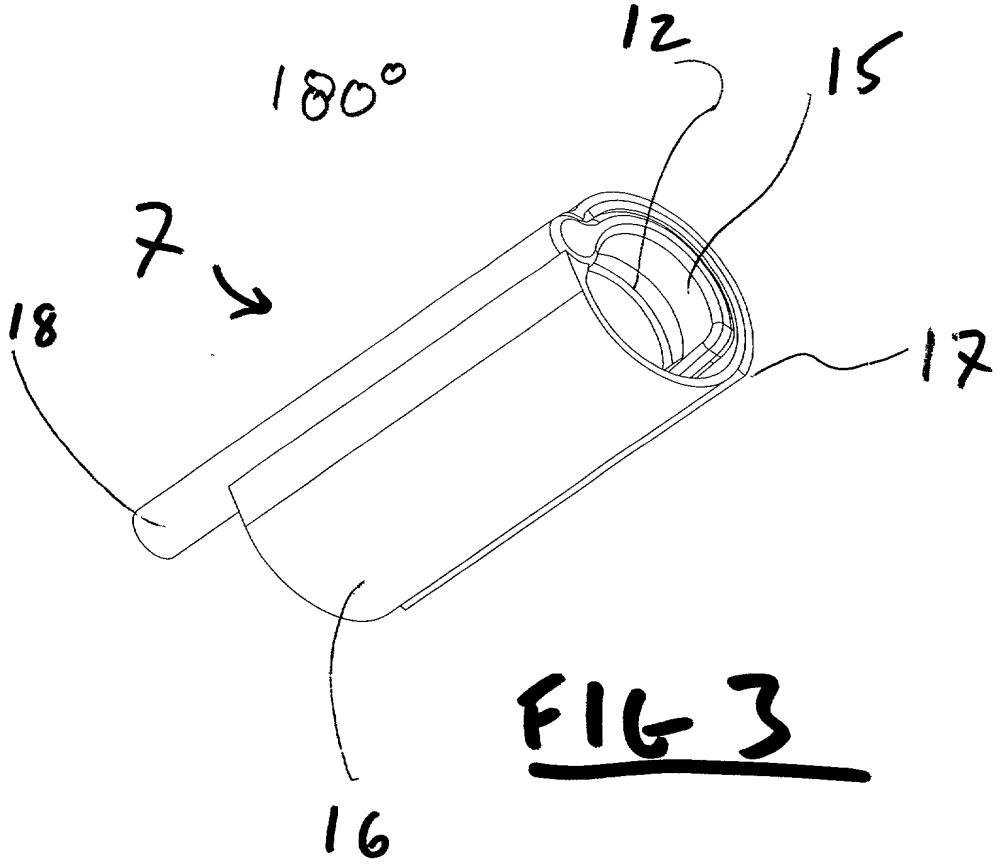


FIG 3

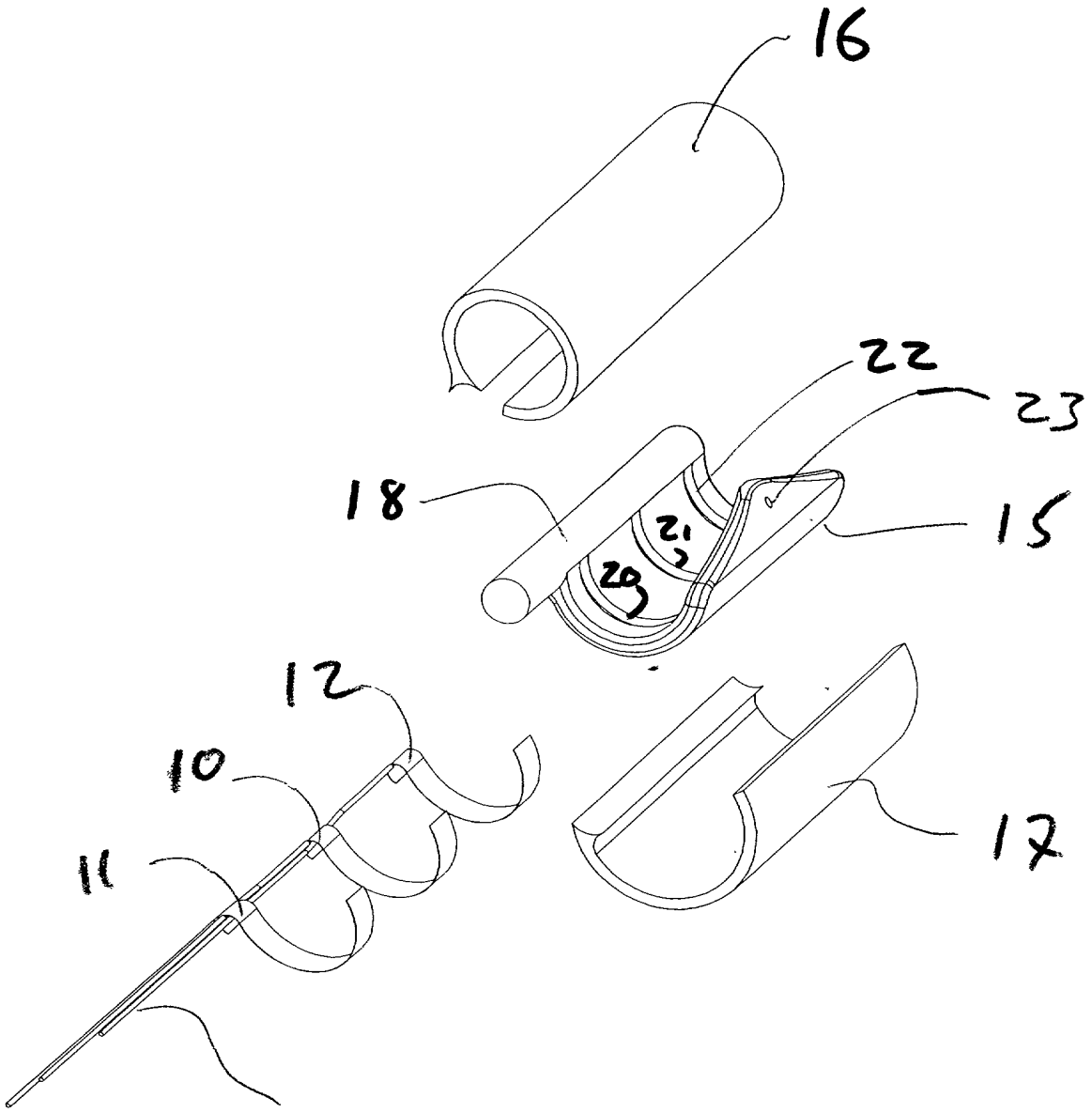


Fig 4A

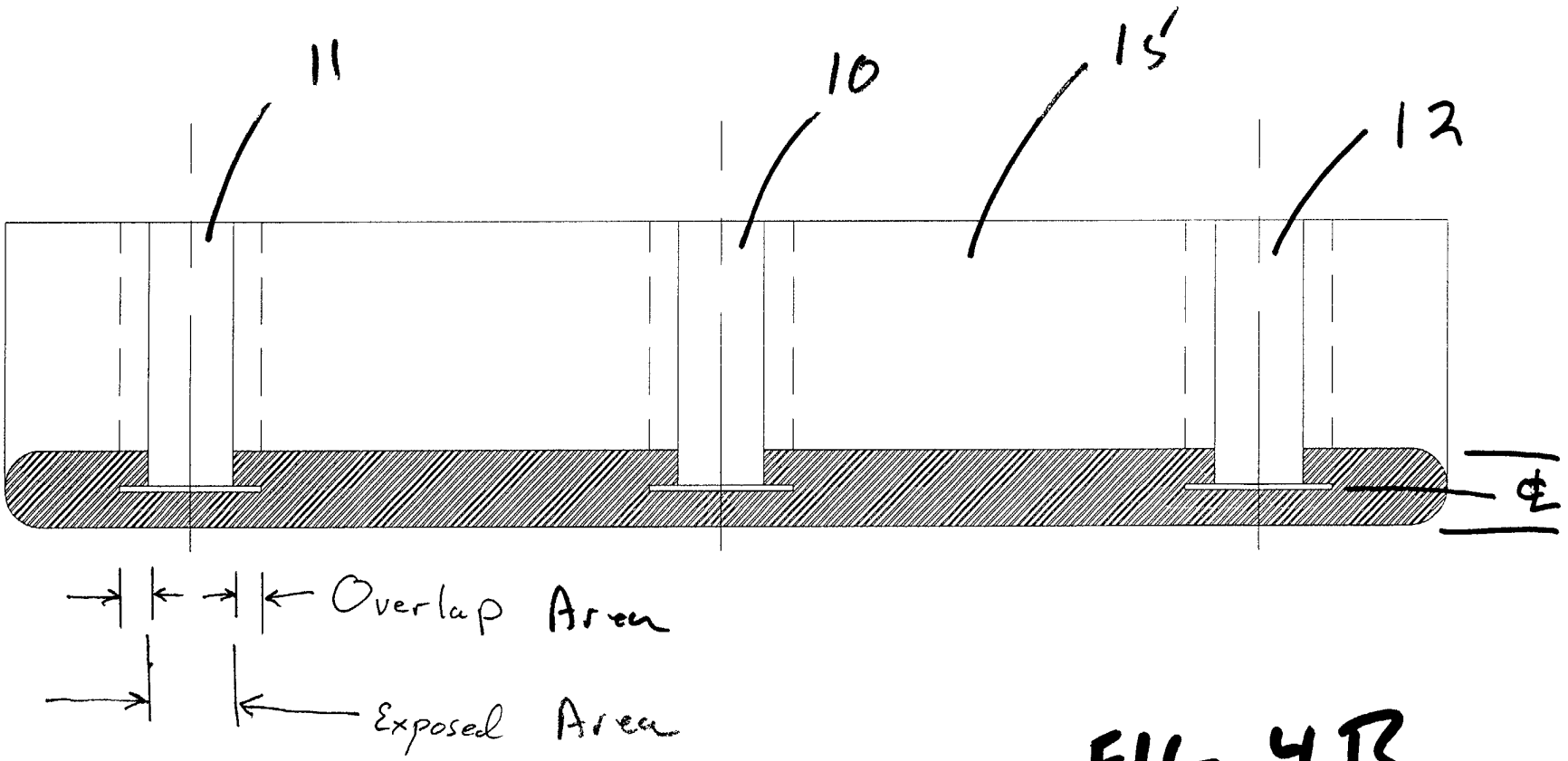


FIG 4B

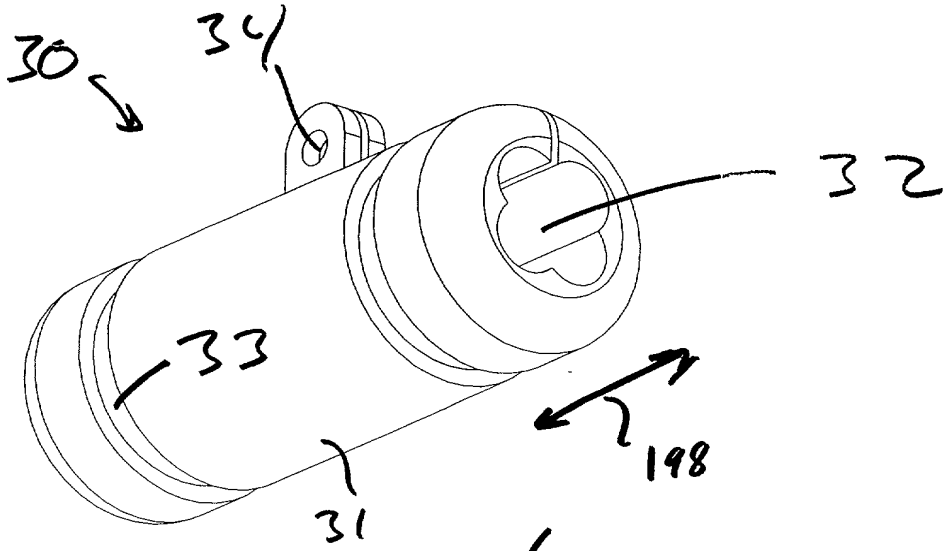


Fig 6

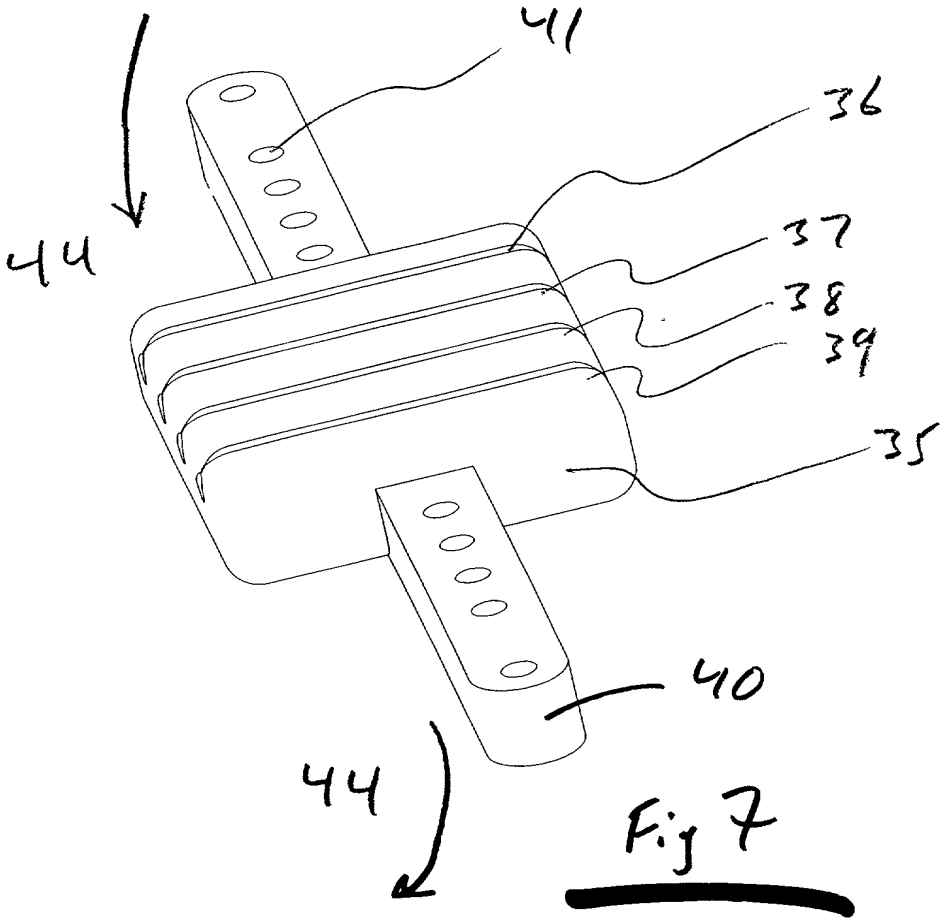


Fig 7

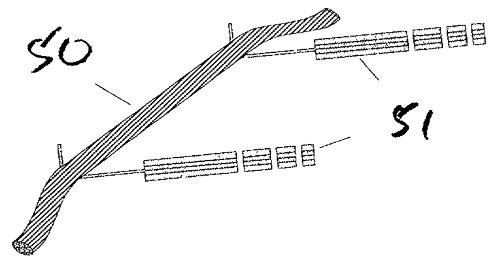
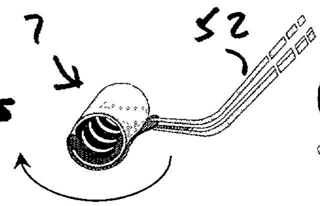


Fig 8

Fig 9



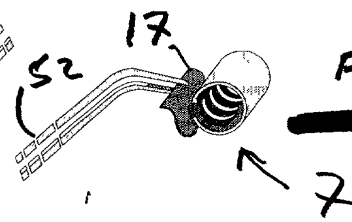


Fig 10

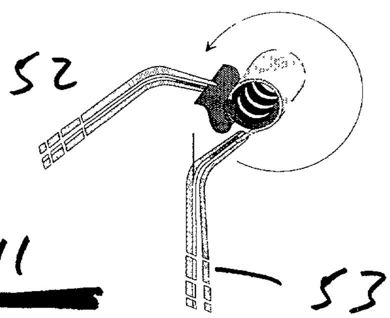


Fig 11

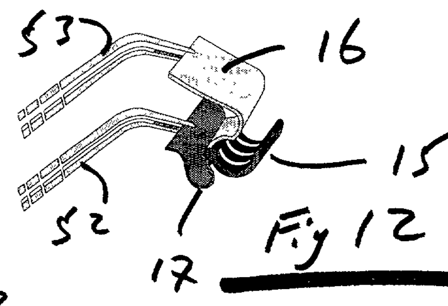
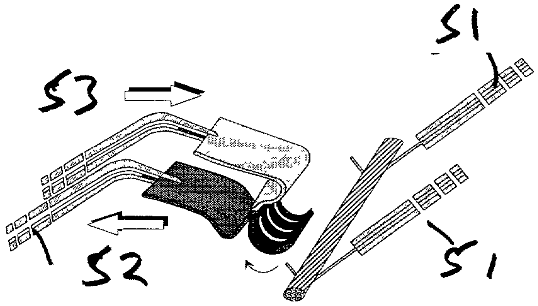


Fig 12

Fig 13



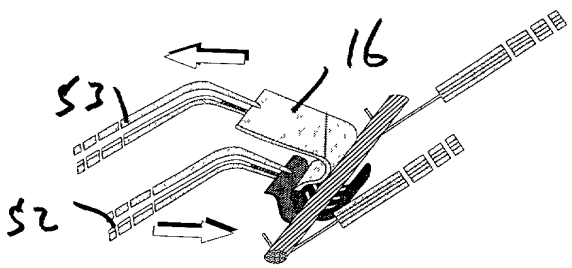


Fig 14

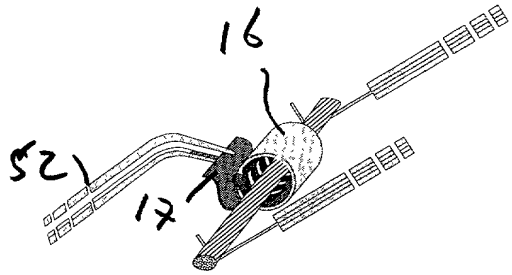


Fig 15

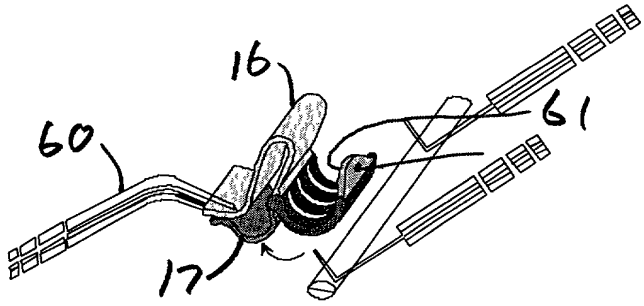


Fig 16

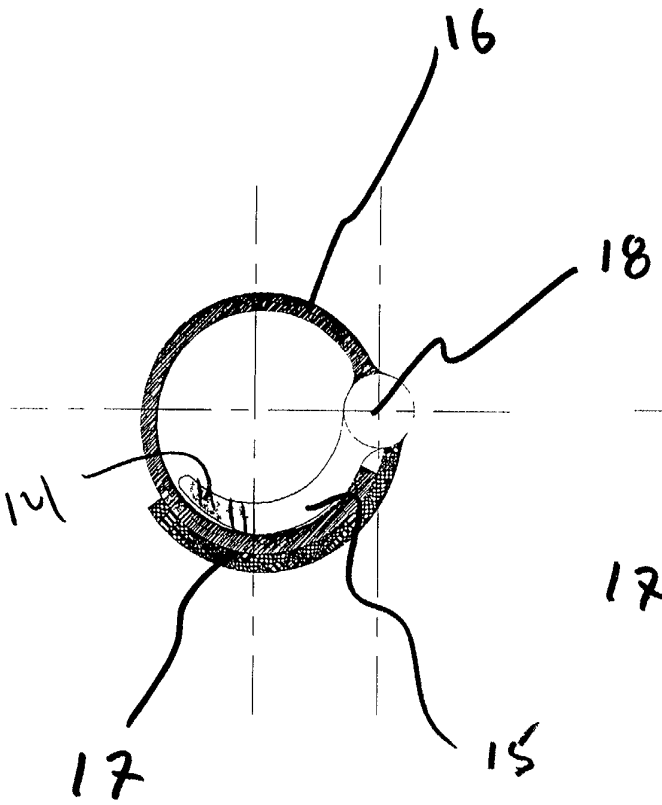


FIG 17A

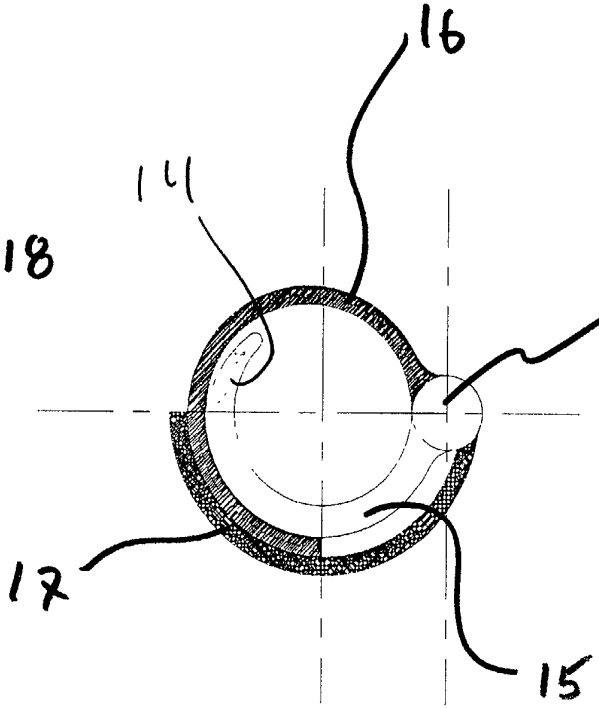


FIG 17B

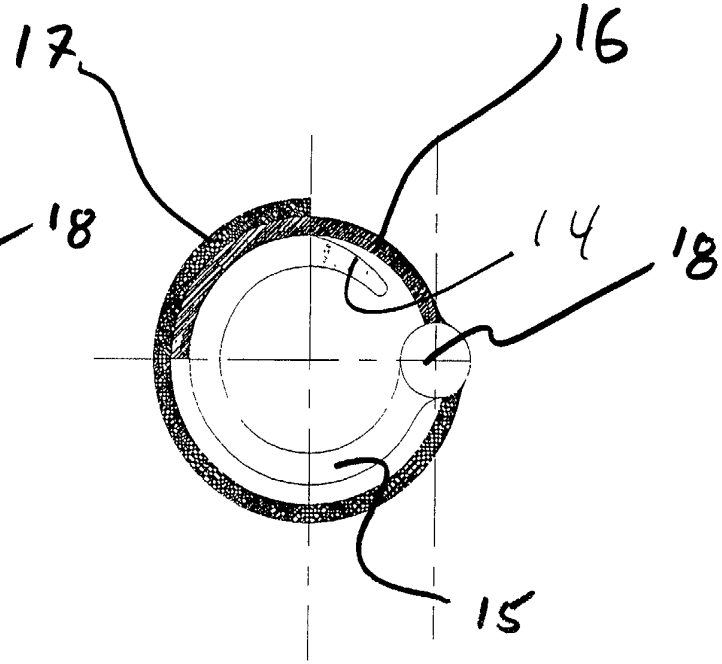


FIG 17C

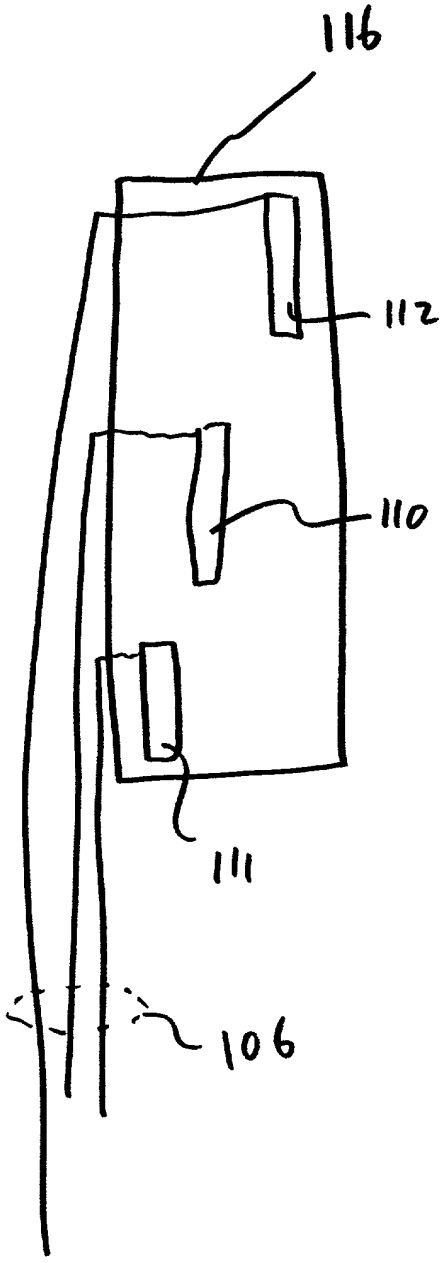


FIG 18A

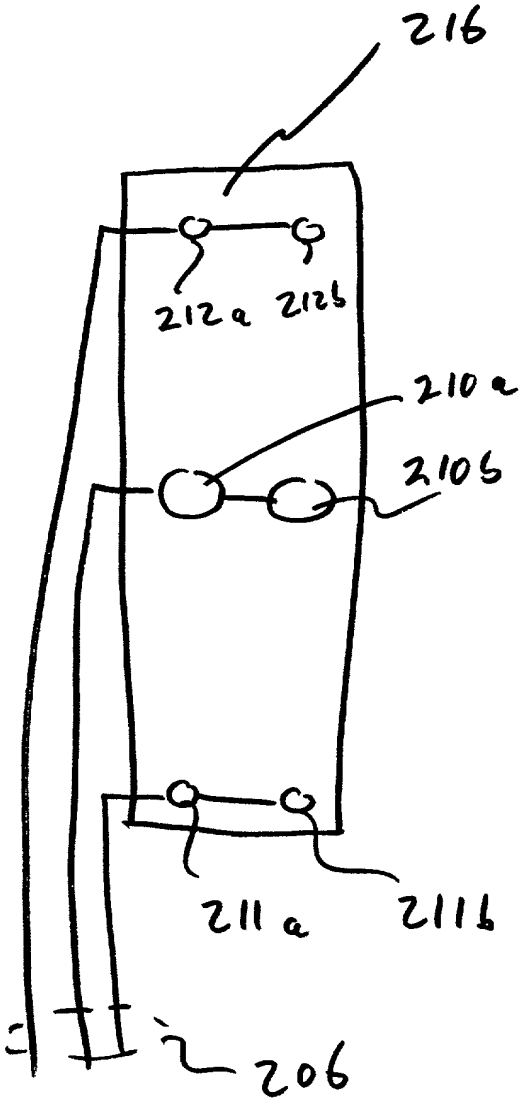


FIG 18B

ATTORNEY DOCKET: P-7326

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: MEDICAL ELECTRICAL LEAD

The specification of which
a. ____ is attached hereto
b. __X__ was filed on MARCH 17, 1997 as application serial no. 08/820,473 and was amended on __ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. ___ filed ___ and as amended on __ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. __X__ no such applications have been filed.
b. ____ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

---

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**
(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton	Reg. No. 22,157	Curtis D. Kinghorn	Reg. No. 33,926
Reed A. Duthler	Reg. No. 30,628	Michael J. Jaro	Reg. No. 34,472
Daniel W. Latham	Reg. No. 30,401	Dianne M.F. Plunkett	Reg. No. 35,649
Michael B. Atlass	Reg. No. 30,606		

Please direct all correspondence in this case to: Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone No. (612) 574-3156

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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SIGNATURE OF INVENTOR 201				DATE Aug. 19, 1997
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SIGNATURE OF INVENTOR 202				DATE August 20 '97
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SIGNATURE OF INVENTOR 203				DATE Sept. 02 '97.

___ Additional pages for fourth and subsequent inventors attached.

X This Declaration ends with this page.